

In re Application of R. J. Steffan, et al.
U.S. Application No. 10/088,991

Attorney Docket No. P23149-A USA
April 5, 2006
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REMARKS

The present Reply is in response to the Office Action, dated December 5, 2005. Reconsideration of the allowability of the present application is requested respectfully.

Status of the Claims

Claims 1 to 6, 9 and 10 were acted upon by the Examiner in the Office Action dated December 5, 2005. No claims have been canceled. Claims 1 and 3 have been amended. Claims 14 and 15 have been added. Accordingly, Claims 1 to 6, 9, 10, 14, and 15 are presented for examination.

Support for Amendments to the Specification

The caption Table 3 has been amended for editorial reasons. No new matter has been added.

Support for Amendments to the Claims

Claims 1 and 3 have been amended to improve clarity.

Support for new claims 14 and 15 are found throughout the application and particularly in Table 5 (pages 47 and 48) and in Table 2 (page 23).

No new matter has been added to the claims.

ARGUMENTS

In response to the Examiner's Office Action dated December 5, 2005, Applicants respectfully traverse the Examiner's rejection of Claims 1 to 6, 9 and 10.

Summary of the Rejections

Claims 3 to 6 and 9 stand rejected under 35 U.S.C. §112, first paragraph (written description).

Claims 1 to 4, 9 and 10 stand rejected under 35 U.S.C. §112, second paragraph.

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The §112, First Paragraph (Written Description), Rejections of Claims 3 to 6 and 9

Claims 3 to 6 and 9 stand rejected under 35 U.S.C. §112, first paragraph, for failing to demonstrate that, at the time of filing, Applicants were in possession of the presently claimed invention. In particular, the Examiner asserts that Applicants have not demonstrated possession of the genus of mutated monooxygenases.

Applicants respectfully traverse the rejection. The “Guidelines for Examination of Patent Applications under the 35 U.S.C. §112, ¶1, ‘Written Description’ Requirement” (66 Fed. Reg., Vol. 66, No. 4p, 1099-1111 (Jan. 5, 2001)) identify the factors to be analyzed to determine if an inventor had possession of a claimed invention. The factors include 1) the level of skill and knowledge in the art, 2) complete or partial structure, 3) physical and/or chemical properties, 4) functional characteristics, 5) the correlation between structure and function, and 6) the method of making the claimed invention. Furthermore, the guidelines indicate that combinations of any of these characteristics can demonstrate possession of the claimed invention. In view of the above factors, Applicants submit that the written description requirement has been met.

With regard to the level of skill and knowledge in the art, Applicants submit that the level of skill and knowledge in the art of the present application is high. The level of skill and knowledge in the art is also high in regard to mutating monooxygenases in order to alter their enantiomeric ratios. In fact, methods for mutating enzymes have been well known in the art for many years and the field of molecular biology has advanced to the point where mutagenesis is a routine matter.

With regard to complete or partial structure, Applicants have provided information on microorganisms comprising strains of monooxygenases (and their enantiomeric ratios; Table 3; page 23) as well as mutated monooxygenases (Table 5; pages 47 and 48). In addition, Figures 15 and 16 provide structural information related to monooxygenases (amino acid sequences and nucleic acids encoding monooxygenases).

Similarly, the physical and/or chemical properties, the functional characteristics, and correlation between structure and function of the active agents listed above are also readily ascertainable to one of skill in the art. In particular, using the monooxygenases from the disclosed organisms (page 14, line 9, to page 15, line 8), various alkene substrates can be

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converted into epoxides (page 13, line 4, to page 14, line 8). The enantiomeric ratios of such epoxide generation can be measured using the disclosed methods (page 21, line 1, to page 24, line 2). Accordingly, the structure and/or chemical properties (the monooxygenases from the disclosed organisms) and a functional characteristic (conversion to an epoxide) have been described.

With regard to methods of making the invention, the methods of making the invention are clear and enabled since applicants discloses a method of measuring the enantiomeric ratios as well as methods of mutating the monooxygenases. Also, at least fifteen examples of mutated monooxygenases are disclosed. In addition, methods of mutating the monooxygenases are also disclosed (page 11, line 18 to page 13, line 3).

The Examiner has asserted that the claimed "mutated" enzyme is not adequately described in the specification. The skilled artisan would recognize that a mutated enzyme is an enzyme having a modified polypeptide sequence. Such a modification distinguishes the mutated enzyme from the native enzyme. As noted above, a list of mutated monooxygenases and their corresponding enantiomeric ratios is found in Table 5 of the application. Accordingly, the term "mutated" adequately defines the scope of the claim and Applicants have demonstrated possession of over fifteen different species within this claim scope.

Applicants submit that the combination of the information in the application as described above demonstrates that applicants was in possession of mutated monooxygenases useful for preparing epoxides. Accordingly, Applicants respectfully request that the rejection of claims 3 to 6 and 9 under 35 U.S.C. §112, first paragraph (written description), be withdrawn.

The §112, Second Paragraph, Rejections of Claims 1 to 4, 9, and 10

Claims 1 to 4, 9 and 10 stand rejected under 35 U.S.C. §112, second paragraph, as containing new subject matter and for failing to particularly point out and distinctly claim the invention. In response, Applicants have amended independent Claims 1 and 3 to clarify the language of the claims (claims 2 and 4 depend directly from claims 1 and 3, respectively).

Claims 9 and 10 have been rejected because the recitation "a desired ratio" is indefinite. The Examiner asserts that it is unclear what ratio the Applicants are attempting to

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produce and what conditions are required for the production thereof.

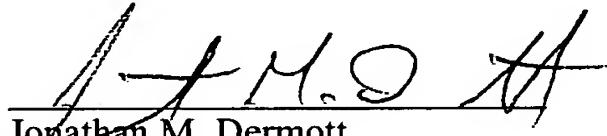
Applicants respectfully traverse the rejection.

The term "desired ratio" is not unclear. The term refers to that ratio of enantiomers suitable for a particular purpose or application. Using Table 5, one skilled in the art would recognize that if, for example, a 1:2 R:S butadiene epoxide ratio were sought, then wild type T4MO can be utilized. As another example, if a 3:2 R:S butadiene epoxide ratio were sought, then I100K T4MO can be utilized. Applicants have enabled methods for producing many different enantiomeric ratios and have also enabled methods for producing mutated monooxygenases that produce unknown enantiomeric ratios. The term "desired ratio" is clear in that it covers these ranges.

Accordingly, Applicants respectfully requests that the rejection of claims 1 to 4, 9 and 10 under 35 U.S.C. §112, second paragraph, be withdrawn.

A favorable action on the merits is requested respectfully.

Respectfully submitted,



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